



Customer No. 22,852  
Attorney Docket No. 10279.0020-02

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	
	)	
Brett HAARALA et al.	)	Group Art Unit: 3767
	)	
Application No.: 09/690,473	)	Examiner: Benjamin Huh
	)	
Filed: October 18, 2000	)	Confirmation No.: 1891
	)	
For: GUIDEWIRE COMPATIBLE PORT	)	
AND METHOD FOR INSERTING	)	
SAME	)	

**Mail Stop AF**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

For the following reasons, Applicants respectfully request pre-appeal brief review of the claim rejections in the final Office Action dated August 22, 2006.

**The Section 102(e) Rejection Based on Villani Should Be Withdrawn**

The rejection of claims 60, 61, 63-68, 70-72, 74-79, 113, and 114 under 35 U.S.C. § 102(e) based on U.S. Patent 5,848,989 to Villani ("Villani") should be withdrawn because Villani does not disclose the subject matter recited in independent claims 60, 70, 113, and 114.

**Independent Claims 60 and 70 Are Allowable Over Villani**

Villani fails to disclose an access port device including, among other features, an "access site" and an "entry site . . . , wherein the device is configured to permit access to [a] reservoir via the access site," as recited in claims 60 and 70. Contrary to the assertion in the Office Action at p. 3, reference numeral 6 of Villani does not constitute an access site.

Reference numeral 6 of Villani refers to an enclosed, hollow body portion that receives a septum 4 and a hollow core 3. See Villani at col. 3, lines 32-33 and col. 4, lines 21-26.

Villani does not disclose any configuration that permits access to a reservoir via the enclosed, hollow body portion 6, and thus the enclosed, hollow body portion 6 does not correspond to the access site recited in claims 60 and 70.

The final Office Action and the Advisory Action dated December 19, 2006, fail to provide any meaningful explanation of why the Examiner has equated Villani's enclosed, hollow body portion 6 with the access site recited in claims 60 and 70. Although the final Office Action at page 3 cites Figs. 2 and 3 of Villani, these drawing figures of Villani do not illustrate a configuration permitting access to a reservoir via the enclosed, hollow body portion 6. In particular, the assembled view of Fig. 3 shows both the septum 4 and the core 3 inserted into the enclosed, hollow body portion 6 without having any configuration that permits access to a reservoir via the portion 6.

Applicants respectfully disagree with the apparent assertion associated with the Examiner's statement that "the access site also does not state what it necessarily gives access to." Office Action at 3. Claims 60 and 70 specifically recite a configuration that "permit[s] access to a reservoir via the access site" and, thus, require the recited access site to permit access to a reservoir. The claim recitation of a "device [that] is configured to permit access to [a] reservoir via an access site" is a positive structural limitation that must be given patentable weight. Nothing supports the Examiner's labeling of this recitation as a "negative limitation" and, more importantly, even if it could be considered as a negative limitation (which it cannot), the limitation still must be given patentable weight.

#### **Independent Claims 113 and 114 Are Allowable Over Villani**

Villani also does not disclose the system recited in claims 113 and 114, including, among other features, one of a guidewire and a stylet in combination with an access port

device having a configuration that “permit[s] insertion of said one of a guidewire and a stylet through [a] body portion and into [an] outlet.” Contrary to the apparent assertion in the final Office Action at page 2, reference numeral 13 of Villani refers to a needle, which is not necessarily the same as, and does not disclose, “one of a guidewire and a stylet,” as positively recited in claims 113 and 114. Moreover, even hypothetically if the needle 13 of Villani were to be considered as being one of a guidewire and a stylet, Villani does not disclose a configuration that would permit inserting the needle 13 “through [a] body portion and into [an] outlet,” as recited in claims 113 and 114. For example, Villani lacks any disclosure of a configuration that permits an end of needle 13 to pass through the outlet 9. Accordingly, Villani does not disclose the system recited in claims 113 and 114, and claims 113 and 114 are allowable over Villani.

#### **The Section 102(b) Rejection Based on Hilger Should Be Withdrawn**

The rejection of claims 60, 61, 63-65, 68, 70-72, 74-79, 113, and 114 under 35 U.S.C. § 102(b) based on Hilger should be withdrawn because Hilger does not disclose all of the features recited in independent claims 60, 70, 113, and 114.

#### **Independent Claim 60 is Allowable Over Hilger**

Hilger does not disclose an entry site “disposed opposite [an] outlet and being configured to permit insertion of one of a guidewire and a stylet through [a] body portion and into [an] outlet,” as recited in claim 60. Contrary to the assertion in the final Office Action at page 4, reference numeral 12 of Hilger does not correspond to the entry site recited in claim 60. Reference numeral 12 of Hilger refers to a lumen. The lumen 12 is not “disposed opposite an outlet,” as recited in claim 60. Moreover, nothing supports the assertion in the Office Action at page 4, regarding the purported “shape and size and position” of the lumen 12 and the alleged “recogni[tion] by persons of ordinary skill in the art.” Accordingly, Hilger lacks disclosure of an entry site “disposed opposite [an] outlet and being configured

to permit insertion of one of a guidewire and a stylet through [a] body portion and into [an] outlet,” as recited in claim 60.

Claim 60 is also allowable over Hilger because Hilger does not disclose a device, including “an outlet configured to be in flow communication with [a] reservoir; an access site . . . ; and an entry site . . . configured to permit insertion of one of a guidewire and a stylet through the body portion and into the outlet, . . . wherein the device is configured to permit access to the reservoir via the access site,” as recited in claim 60. The final Office Action at page 4 erroneously equates reference numeral 37 of Hilger with the outlet recited in claim 60. Reference numeral 37 of Hilger is an opening in a boss 34 that receives a catheter 30. Hilger at col. 3, lines 45-46. The opening 37 does not correspond to the outlet recited in claim 60 because the opening 37 is not “configured to be in flow communication with [a] reservoir,” as recited in claim 60. For example Figs. 4-6 clearly show the catheter 30 making contact with the entire inner surface of the opening 37, and thus preventing any fluid communication between the opening 37 and the cavity 23’, which the Examiner equates with the recited reservoir. Consequently, Hilger does not disclose “an outlet configured to be in flow communication with [a] reservoir” in combination with the other features recited in claim 60.

#### **Independent Claim 70 is Allowable Over Hilger**

Claim 70 recites a device including a reservoir, “an entry site . . . configured to permit access to the reservoir[,] . . . and an access site . . . configured to permit access to the reservoir.” In other words, claim 70 requires both an entry site and an access site to be configured to permit access to the same reservoir. Applicants respectfully submit that claim 70 is allowable over Hilger because Hilger does not disclose such configurations. For example, Hilger’s lumen 12, which the Examiner has attempted to equate with the recited

entry site, doesn't have a configuration permitting access to Hilger's cavity 23', which the Examiner has equated with the recited reservoir.

**Independent Claims 113 and 114 Are Allowable Over Hilger**

As mentioned above, each of claims 113 and 114 positively recites "one of a guidewire and a stylet" in combination with an access port device having a configuration that "permit[s] insertion of said one of a guidewire and a stylet through [a] body portion and into [an] outlet . . . ." Hilger does not disclose this combination of features. For example, Hilger does not mention or otherwise teach the recited "one of a guidewire and stylet," as recited in claims 113 and 114.

**All of the Dependent Claims Are Allowable Over Villani and Hilger**

Claims 61, 63-68, 71, 72, and 74-79 depend from either claim 60 or claim 70 and, thus, those dependent claims should also be allowable.

**Conclusion: The Application is in Condition for Allowance**


For at least these reasons, all of the claim rejections should be withdrawn and the application should be allowed.

Please grant any extensions of time required to enter this Pre-Appeal Brief Request for Review and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: January 22, 2007

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